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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. CONFIRMATION NO. 09/993,756 11/05/2001 PF-0111-3 CON 9899 Bernard Bailleul 27904 7590 10/03/2003 EXAMINER INCYTE CORPORATION (formerly known as Incyte ULM, JOHN D Genomics, Inc.) ART UNIT PAPER NUMBER 3160 PORTER DRIVE PALO ALTO, CA 94304

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary		
	09/993,756	BAILLEUL ET AL.
	Examiner	Art Unit
The MAILING DATE of this communication ann	John D. Ulm	1646
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on		
, —	is action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4)⊠ Claim(s) <u>1-57</u> is/are pending in the application	١.	
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) 1-57 are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) .

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Claims 1 to 57 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1, 2, 17, 18 and 56, drawn to an isolated polypeptide, classified in class 530, subclass 350.
- II. Claims 3 to 7, 9, 10, 12, 13 and 57, drawn to an isolated polynucleotide and method of use, classified in class 435, subclass 69.1.
- III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 2.
- IV. Claims 11, 31, 32, 34, 37, 38 and 40 to 43, drawn to an antibody that binds to a putative receptor polypeptide, classified in class 530, subclass 388.22.
- V. Claims 14 to 16, 28, 29 and 46 to 55, drawn to a method of nucleic acid analysis and apparatus for such, classified in class 435, subclass 6.
- VI. Claim 19, drawn to a method of treatment by administering a putative receptor polypeptide, classified in class 514, subclass 2.
- VII. Claims 20, 23, 26 and 27, drawn to a biospecific binding assay, classified in class 436, subclass 501.
- VIII. Claims 21 and 22, drawn to an agonist of unspecified constitution and method of use, classification undeterminable.
- IX. Claims 24 and 25, drawn to an antagonist of unspecified constitution and method of use, classification undeterminable.

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X. Claims 30 and 44, drawn to an immunoassay, classified in class 436, subclass 536.

- XI. Claims 33 and 35, drawn to a method of diagnosis by administering an antibody, classified in class 424, subclass 139.1.
- XII. Claims 36 and 39, drawn to a method of making an antibody, classified in class 424, subclass 184.1.
- XIII. Claim45, drawn to a method of purifying a protein by employing an antibody, classified in class 530, subclass 413.

The inventions are distinct, each from the other because:

The polypeptide of invention I, the polynucleotide of invention II, the transgenic organism of invention III, the antibody of invention IV, the agonist of invention VIII and the antagonist of invention IX are six different and distinct chemical compounds, each of which can be made and used without the others. They lack unity of invention because they do not have a common utility that is based upon a shared technical feature or combination of features lacking from the prior art.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of invention II can be used to produce a protein, which is materially different from the analytical process of invention V.

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Invention I is related to inventions VI, VII and XII as product and processes of use. They are shown to be distinct because the method of treatment that is invention, the binding assay of invention VII and the method of producing an antibody that is invention XII are three materially different methods of using the polypeptide of invention I because they achieve different objectives by employing different method steps.

The antibody of invention IV is related to the immunoassay of invention X, the diagnostic method of invention XI and the purification method of invention XIII as product and processes of use. They are shown to be distinct because the method of diagnosis by administering an antibody that is invention X, the method of detecting an antigen in a sample that is invention XI and the method of purifying a polypeptide that is invention XIII are materially different methods of using the antibody of invention IV because they achieve different objectives by employing different method steps.

Inventions II and XIII are each related to the isolated polypeptide of invention I as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of invention I can be isolated from a natural source by employing the method of invention XIII, for example, which is materially different from the recombinant method of invention II.

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Inventions XII and VI are related as process of making and product made. The inventions are distinct because the product as claimed can be made by another and materially different process, as indicated by claim 43.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM PRIMARY EXAMINER GROUP 1000